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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

June 22, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert A. Ostertag
President/CEO
Foster and Gallagher Inc
6523 North Galena Road
Peoria, IL 61632

PUNCED

Ref: # Den-98-14

Dear Mr. Ostertag:

This letter is in reference to the marketing and distribution of products by Walter Drake & Sons, Inc., 4510 Edison Ave., Colorado Springs, Colorado, 80940. Walter Drake & Sons, Inc. is a subsidiary owned by your firm which markets the products BIO-EAR and NutriSurge via catalog. The Walter Drake catalog is product labeling which makes therapeutic claims for BIO-EAR and NutriSurge, causing these products to be drugs under section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act).

Objectionable claims for BIO-EAR found in the Walter Drake catalog include the following: all references to "tinnitus," "ringing in the ears." "...make a difference in the irritating ringing and buzzing noise by stimulating the blood supply to nerves in the ear," "...offered an unquestionable difference in the symptoms."

Objectionable claims for NutriSurge found in the Walter Drake Catalog include: "...by increasing blood flow to prime areas of the male anatomy" and "Studies show the ingredient B-15(dimethylglycine) can provide protection from viral infections."

BIO-EAR and NutriSurge are "new drugs" because they are not generally recognized by experts as safe and effective for their intended use [§ 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [§ 505(a) of the Act]. These drugs are misbranded because their labeling does not have adequate directions for the conditions for which they are offered [§ 502(f)(1) of the Act]. In addition, the labeling for these products is false and misleading because it suggests that these products are safe and effective for their intended uses, when in fact, this has not been established [§ 502(a) of the Act].

Review of our files show Walter Drake was inspected in 1991 and informed that, because of the claims made in the Walter Drake catalog, the product BIO-EAR was a drug. In letters to FDA in February, March, and April of 1992, Mr. Herbert Lawonn, General Manager, agreed to remove the violative drug claims. He then decided that Walter Drake could not sell BIO-EAR without the drug claims, and discontinued the sale of BIO-EAR. We are quite concerned that Walter Drake reversed its position and began the marketing of this product again, with identical claims, after advising us that they would no longer promote violative product.

During the current inspection, Walter Drake provided FDA with "FDA Guaranty" forms signed by the suppliers of BIO-EAR and NutriSurge. These forms contain false statements that the products are not adulterated, misbranded, or in violation of the provisions of the Act. Such forms do not absolve Walter Drake & Sons, Inc. from the responsibility of ensuring that its products are marketed in accordance with the provisions of the Act. Via copy of this letter, we are advising both [redacted] (BIO-EAR) and [redacted] (NutriSurge) that these products are unapproved new drugs, misbranded drugs, and the object of a false guaranty.

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to the Food and Drug Administration, Denver District Office, Attention: Shelly L. Maifarth, Compliance Officer, at the above address.

Sincerely,

Gary C Dean
District Director

cc: Jon Medved, President
Walter Drake & Sons., Inc.
4510 Edison Avenue
Colorado Springs, CO 80940

(Nutri-Surge)

[redacted]

(Bio-Ear)

[redacted]

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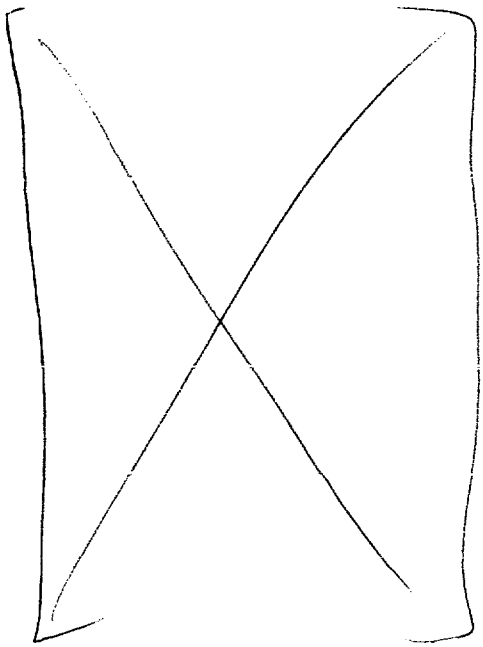

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